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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,877	07/27/2007	Indriati Pfeiffer	4007620-173752	2936

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COLUMBUS, OH 43215

EXAMINER

SCHULTZ, JAMES

ART UNIT	PAPER NUMBER
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1633

MAIL DATE	DELIVERY MODE
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03/09/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/590,877	Applicant(s) PFEIFFER ET AL.	
	Examiner J. Douglas SCHULTZ	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-27 is/are pending in the application.
- 4a) Of the above claim(s) 18-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6,9-14 and 16 is/are rejected.
- 7) ☒ Claim(s) 5, 7, 8, 15, and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed December 14, 2010 has been considered. Rejections and/or objections not reiterated from the previous office action mailed September 14, 2010 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application contains claims 18-27 drawn to an invention nonelected with traverse in the reply filed on July 6, 2010. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 6, 9-14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Tyagi et al. (WO 2002/33045, of record). This rejection is over the same reference of record, but has been restated to include claims that have been amended significantly. Those arguments considered to be pertinent to this rejection are responded to following.

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The claims embrace an oligonucleotide that has two strands hybridized to each other and having at least two hydrophobic anchoring moieties capable of being attached to a lipid membrane, wherein said hydrophobic anchoring moieties are located at terminal ends of the strands, and which are adjacent to each other. The two strands may be hybridized to each other in a manner that leaves the first strand free to hybridize with a third strand.

The claims also embrace an oligonucleotide comprising at least two hydrophobic anchoring moieties selected from steroids, fatty acids, hydrophobic peptides and lipids, or wherein the hydrophobic anchoring moieties is cholesterol or a derivative thereof. The hydrophobic anchoring moiety may be spaced apart from the duplex section by a spacing group or a sufficient number of non-hybridized nucleic acid units.

The claims embrace an oligonucleotide comprising a hydrophobic moiety adapted and available to be linked to a surface immobilized linker or to another lipid membrane attached linker. The claims embrace an oligonucleotide according to the invention which is immobilized to a surface, or which has a second strand longer than a first, or comprises a section of PNA monomers.

Tyagi et al. teaches a duplexed oligonucleotide, wherein each oligonucleotide is covalently bound to a cholesterol moiety at their terminal ends which are adjacent to each other (see figure 4 for example).

Tyagi et al. is considered to teach an oligonucleotide comprising at least two hydrophobic moieties adapted and available to be linked to a surface immobilized linker or to another lipid membrane attached linker, since the oligonucleotide of Tyagi teaches that one strand is longer

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than the other, which is therefore capable of binding with specificity to another oligonucleotide. Note that the claim requires only that the oligonucleotide is capable of attaching with specificity, and does not require that it actually is bound to anything with specificity. Tyagi al. teach an oligonucleotide as claimed instantly, wherein a first strand is longer than a second, and has a duplex involving the terminal end of the second strand. (See Example 1 for example), and an oligonucleotide with further comprises a section of peptide nucleic acids (PNA) capable of forming PNA-peptide complexes. Regarding amended claim 11, which recites "...each hydrophobic anchoring moiety is spaced apart from the duplex section bya sufficient number of non-hybridized nucleic acid units", it is maintained that figure 3 of Tyagi teach the claimed oligo having a sufficient number of non-hybridized units, which could be 1, particularly given the lack of a definition of what would be sufficient. Tyagi teaches an oligo meeting all the claimed limitations and having at least one non-hybridized nucleotide pair. See figure 3 of Tyagi.

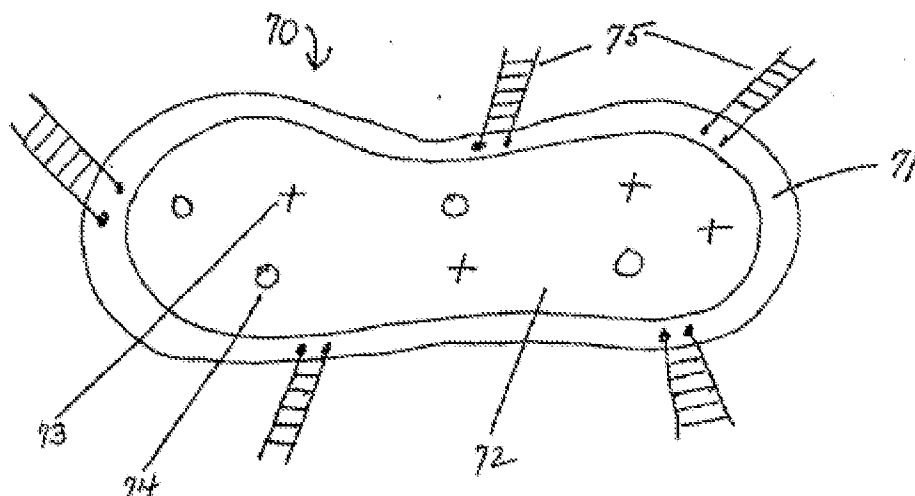
Applicant's arguments of December 14, 2010 have been fully considered, but are not convincing. Applicants argue that contrary to the oligonucleotide structure of claim 1, which requires both a duplex section and at least two hydrophobic anchoring moieties capable of being attached to a lipid membrane, the oligonucleotides of Tyagi are only duplexed after they are attached to cells, liposomes or lipid particles. Applicants state that they find no apparent reasoning in the evidence of record that would have led one of ordinary skill in the art to modify the teachings of Tyagi et al to result in the oligonucleotide structures of claims 1-17, including both a duplex section and at least two hydrophobic anchoring moieties capable of being attached to a lipid membrane. Applicants thus conclude that Tyagi et al fail to render the oligonucleotide structures of claims 1-17 obvious.

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In response, it is noted that the present claims are directed to compounds. The question at issue is whether the reference of Tyagi et al. teach all the elements of claims, or whether any differences would have been obvious to one of ordinary skill in the art. Claim 1 is reproduced as follows:

1. (Currently Amended) An oligonucleotide structure comprising a first strand of nucleic acid and a second strand of nucleic acid, the first and second strands being hybridized to each other in a duplex section, and at least two hydrophobic anchoring moieties capable of being attached to a lipid membrane, wherein a terminal end of the first strand is not part of the duplex section and is free from a hydrophobic moiety and wherein the hydrophobic anchoring moieties are covalently attached to adjacent terminal ends of the first and second strands, respectively.

The structure of Tyagi is reproduced below:



The structure marked "75" is a double stranded DNA (i.e. an oligonucleotide structure comprising a first strand of nucleic acid and a second strand of nucleic acid, the first and second strands being hybridized to each other in a duplex section). Tyagi teaches at page 8 that one strand is 68 nucleotides long, is labeled at its 5'-end with cholesterol, and the other strand is 74 nucleotides long, and labeled with cholesterol at its 3'-end. Tyagi teaches there is a 6 nucleotide overhang. Thus, Tyagi teaches the presence on the double stranded DNA of two hydrophobic

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moieties that are adjacent to each other, wherein one end is not apart of the duplex section. Clearly, since the hydrophobic moieties are attached in a lipid membrane, they are capable of such. It would thus appear that all elements of applicant's claim 1 are met by this teaching of Tyagi.

The argument that the structure of Tyagi was made after the single stranded oligos were attached to their respective lipid bilayers does not appear to matter under 35 U.S.C. § 102(b), since all elements are present. Since this is not a method claim, there is no weight given to how the compound was made, as long as it meets the limitations of the claimed compound, which this structure of Tyagi is considered to do. The rejection is considered proper therefore.

Allowable Subject Matter

Claims 5, 7, 8, 15, and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James (Doug) Schultz, PhD whose telephone number is (571)272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James (Doug) Schultz/
Primary Examiner, Art Unit 1633

Application Number
10/590,877



U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

EXAMINER'S CASE ACTION WORKSHEET

Copy (Ctrl+C)	Palm Transaction Code		Legal Instrument Examiner
	1340 79285163310590877		

CHECK TYPE OF ACTION

DATE OF COUNT

<input type="checkbox"/> Non-Final Rejection	<input type="checkbox"/> Restriction/Election Only	<input checked="" type="checkbox"/> Final Rejection
<input type="checkbox"/> Ex Parte Quayle	<input type="checkbox"/> Allowance	<input type="checkbox"/> Advisory Action
<input type="checkbox"/> Examiner's Answer	<input type="checkbox"/> Reply Brief Noted	<input type="checkbox"/> Non-Entry of Reply Brief
<input type="checkbox"/> Defective Notice of Appeal	<input type="checkbox"/> Interference Disposal SPE _____ (Approval for Disposal)	<input type="checkbox"/> Suspension (Examiner-Initiated) SPE _____ (initial)
<input type="checkbox"/> Defective Appeal Brief	<input type="checkbox"/> SIR Disposal (use only after FAOM)	<input type="checkbox"/> Supplemental Examiner's Amendment
<input type="checkbox"/> Miscellaneous Office Letter (With Shortened Statutory Period Set)	<input type="checkbox"/> Notice of Non-Responsive Amendment (With One Month Time Period set)	<input type="checkbox"/> Miscellaneous Office Letter (No Response Period Set)
<input type="checkbox"/> Abandonment after BPAI Decision	<input type="checkbox"/> Supplemental Action	<input type="checkbox"/> Response to Rule 312 Amendment
<input type="checkbox"/> Letter Restarting Period for Response (e.g., Missing References)	<input type="checkbox"/> Interview Summary	<input type="checkbox"/> Authorization to Change Previous Office Action SPE: _____ (Initial)
<input type="checkbox"/> Abandonment	<input type="checkbox"/> Express Abandonment Date: _____	<input type="checkbox"/> Other

Examiner's Name: J. Douglas SCHULTZ

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